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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/809,920	03/16/2001	Taka-Aki Sato	0575/51902-A-PCT-US/JPW/A	8743

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EXAMINER

SCHMIDT, MARY M

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 07/09/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/809,920	Applicant(s) SATO, TAKA-AKI	
	Examiner Mary Schmidt	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16,20-22,38,39,68 and 90 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-16,20-22,38,39,68 and 90 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-11, 16, 20 and 22, drawn to nucleic acid compositions encoding a rodent (mouse or rat) TREX, such as the nucleic acid sequence of SEQ ID NO:1, which encodes the TREX of SEQ ID NO:2, and vector encoding the nucleic acid sequence of TREX, classifiable in class 435, subclass 320.1; class 536, subclasses 23.1 and 23.5.
 - II. Claims 1-7, 12-16, 21 and 22, drawn to nucleic acid compositions encoding a human TREX, such as the nucleic acid sequence of SEQ ID NO:3, which encodes the TREX of SEQ ID NO:4, and vector encoding the nucleic acid sequence of TREX, classifiable in class 435, subclass 320.1; class 536, subclasses 23.1 and 23.5.
 - III. Claim 38, drawn to the protein comprising the amino acid sequence set forth in Figure 7(B) (the specification teaches on page 10 that the protein is mouse TREX from SEQ ID NO:2), classifiable in class 530, subclass 350.
 - IV. Claim 39, drawn to the protein comprising the amino acid sequence set forth in Figure 8(B) (the specification teaches on page 10 that the protein is human TREX from SEQ ID NO:4), classifiable in class 530, subclass 350.

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- V. Claim 68, drawn to methods of screening for chemical compound inhibitors of TREX, classifiable in class 435, subclass 4.
- VI. Claim 90, drawn to methods of probing for TREX in a sample from a subject having cancer as a diagnostic method for cancer, classifiable in class 435, subclass 6; and class 536, subclass 24.3.

Please Note: Groups III and IV were grouped above as drawn to protein compounds since the preamble of claims 38 and 39 were drawn to proteins comprising amino acid sequences.

However, there is typographical error in claims 38 and 39 since the claims recite the proteins in Figures 7A and 8A, but the sequences in these figures are actually nucleic acid sequences. It has been assumed that Applicant intended to claim the corresponding protein sequences in Figures 7B and 8B. If this assumption was made in error, and Applicant intended to claim the nucleic acid sequences in Figures 7A and 8A in claims 38 and 39, respectively, these claims will be rejoined with Groups I and II upon clarification of this point. Applicant is requested to reply to the instant Official Action with an amendment to claims 38 and 39 so that the intended subject matter is clear.

2. The inventions are distinct, each from the other because of the following reasons:

3. Groups I and II, drawn to nucleic acids, are distinct from Groups III and IV, drawn to proteins. These inventions are distinct because they have different chemical, physical, and functional properties as evidenced by divergent classification, process of making and process of using. For instance, nucleic acid sequences are made of polynucleotides and are found in either

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single or double strands in a helix orientation and composed of either deoxy-ribonucleotides or ribonucleotides. In the genome, the deoxy-ribonucleotides function to encode messenger RNA, the intermediate agent in protein expression, which is composed of ribonucleotides. Nucleic acids have phosphate backbones that are distinct from the backbones of proteins composed of amino bonds. The nucleic acids of Groups I and II are capable of separate manufacture, use or sale as claimed, and are patentable (novel and unobvious) over the proteins of Groups III and IV (though they may each be unpatentable because of the prior art).

4. Group I drawn to nucleic acid sequences encoding TREX from rodent (SEQ ID NO:1) is distinct from Group II drawn to nucleic acid sequences encoding TREX from human (SEQ ID NO:3). The rodent and human TREX sequences in Group I and Group II are restricted from each other because each sequence is patentably distinct as per MPEP 803.04 which states:

"Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions with the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq." It has been determined that 1(ONE) unique nucleic acid sequence constitutes a reasonable number for examination purposes under the present conditions. At present the huge number of submissions of claims directed to various sequences, such as nucleic acids or polypeptides, is so large that the election of 1(one) sequence of this type is now deemed to be

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practically appropriate so as to not overwhelm the examination and search processes for such claims. Thus Group I is restricted from Group II based on their inclusion of patentably distinct TREX nucleic acid sequences.

5. Group III drawn to the protein sequence encoding TREX from Figure 7B is distinct from Group IV drawn to protein sequence encoding TREX from Figure 8B. The protein TREX sequences in Group III and Group IV are restricted from each other because each protein sequence is patentably distinct as per MPEP 803.04 (above), for the same reasons that nucleic acid sequences are distinct, *i.e.* the sequence of one protein sequence is capable of separate manufacture, use or sale, and is patentable (novel and unobvious) over another protein sequence (though they may each be unpatentable because of the prior art). It has been determined that 1(ONE) unique protein sequence constitutes a reasonable number for examination purposes under the present conditions. At present the huge number of submissions of claims directed to various sequences, such as nucleic acids or polypeptides, is so large that the election of 1(one) sequence of this type is now deemed to be practically appropriate so as to not overwhelm the examination and search processes for such claims. Thus Group III is restricted from Group IV based on their inclusion of patentably distinct TREX protein sequences.

6. Any of Inventions I-IV and Invention V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

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product (MPEP § 806.05(h)). In the instant case the TREX nucleic acid and protein products of Groups I-IV may be used in diagnostic methods for detection of the TREX in relation to a physiological condition, that does not require screening for a novel inhibitor of TREX as claimed in the methods of Group V.

7. Any of Inventions I-IV and Invention VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the TREX nucleic acid and protein products of Groups I-V may be used in a method of screening for an agonist or antagonist of TREX, that does not require detection of TREX in relation to a physiological condition.

8. Inventions V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The Invention of Group V is drawn to methods of screening for chemical compound inhibitors of TREX. The Invention of Group VI is drawn to methods of diagnosing cancer via probe detection of TREX sequences after restriction digestion of DNA from a patient having cancer. The methods of screening for novel compounds in Group V thus have different functions than the methods of diagnosis of cancer via detection of TREX in a patient claimed in Group VI.

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9. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their divergent classification and recognized divergent subject matter, and the search required for each of Group I, II, III, IV, V or VI is not required for the other Groups, restriction for examination purposes as indicated is proper.

10. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Mary M. Schmidt*, whose telephone number is (703) 308-4471.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *John LeGuyader*, may be reached at (703) 308-0447.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group Analyst, *Kay Pinkney*, whose telephone number is (703) 305-3553.

M. M. Schmidt
July 6, 2002

